MAY 2 3 2001

K011237

BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet, Inc.
56 East Bell Drive
Warsaw, IN 46582

Contact Person: Dalene T. Binkley
Phone: (219) 372-1612
Fax: (219) 372-1683

Proprietary Name: -LactoSorb® Trauma Plating System
-LactoSorb® Trauma Plating System
-LactoSorb® Trauma Plating System
-LactoSorb® Panels
-LactoSorb® Panels and Fasteners
-LactoSorb® Panels and Fasteners
-LactoSorb® RC Buttress
-LactoSorb® Hand System
-LactoSorb® Sheets
-LactoSorb® Trauma Plating System

Common or Usual Name: resorbable bone plates, meshes, panels/sheets

Classification Name: LactoSorb® Trauma Plating System, Hand System, Panels, and Sheets: plate, fixation, bone (888.3030)

-LactoSorb® RC Buttress: fastener, fixation, biodegradable, soft tissue (888.3040)

Device Product Code: LactoSorb® Trauma Plating System, Hand System, Panels, and Sheets: 87 HRS

-LactoSorb® RC Buttress: 87 MAI

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
219.267.6639

FAX
219.267.8137

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biomet@biomet.com

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Substantially Equivalent Devices:

-LactoSorb® Trauma Plating System (K955729)
-LactoSorb® Trauma Plating System (K960988)
-LactoSorb® Trauma Plating System (K971870)
-LactoSorb® Panels (K974309)
-LactoSorb® Panels and Fasteners (K980927)
-LactoSorb® 20-Hole Adaptation Plate (K981070)
-LactoSorb® Panels and Fasteners (K98439)
-LactoSorb® RC Buttress (K991009)
-LactoSorb® Hand System (K991763)
-LactoSorb® Sheets (K992158)
-LactoSorb® Trauma Plating System (K992355)

Device Description:

The LactoSorb® products (plates, mesh, and sheets) included in the 510(k)s above, can now use a hot sterile saline/water bath for heating and reshaping. Previously, only exposure to LactoSorb® Heat Pack was allowed.

Intended Use:

-LactoSorb® Trauma Plating System (K955729 and K960988):

1)Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2)Comminuted fractures of the frontal sinus wall.
3)Trauma of the midface or craniofacial skeleton.
4)Reconstructive procedures of the midface or craniofacial skeleton.

-LactoSorb® Trauma Plating System (K992355 and K971870):

A. General Indication: trauma procedure of the midface or craniofacial skeleton.

Specific Indications:

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.
3) Pediatric midface or craniofacial trauma
4) LeFort (I, II, III) fractures
5) Orbital floor fractures
6) Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
7) Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

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B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2) LeFort (I, II, III) fractures
3) Tumor reconstruction in midface or craniofacial procedures
4) Bone graft procedures in the midface or craniofacial skeleton
5) Pediatric reconstructive procedures
6) Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
7) Craniotomy flap fixation

-LactoSorb® Panels (K974309):

A. General Indication: trauma procedure of the midface or craniofacial skeleton.

Specific Indications:

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.
3) Pediatric midface or craniofacial trauma
4) Orbital floor fractures
5)Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2) Tumor reconstruction in midface or craniofacial procedures
3) Bone graft procedures in the midface or craniofacial skeleton
4) Pediatric reconstructive procedures
5) Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
6) Craniotomy flap fixation

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-LactoSorb® Panels and Fasteners (K980927) are used to maintain the position of bone fragments in mandibular bone graft procedures and are used in conjunction with rigid internal fixation.

-LactoSorb® Panels and Fasteners (K984390) are used in maintaining the position of bony fragments in pelvic reconstructive procedures. This product is not intended for use in the spine or joint space.

-LactoSorb® Hand System (K991763) is indicated for surgical fixation of closed non-comminuted diaphyseal metacarpal fractures in the presence of appropriate immobilization.

-LactoSorb® Sheets (K992158):

A. General Indication: trauma procedure of the midface or craniofacial skeleton.

Specific Indications:

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.
3) Pediatric midface or craniofacial trauma
4) Orbital floor fractures
5) Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bone.

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2) Tumor reconstruction in midface or craniofacial procedures
3) Bone graft procedures in the midface or craniofacial skeleton
4) Pediatric reconstructive procedures
5) Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
6) Craniotomy flap fixation

C. Mandible Indication: Used to maintain the position of bony fragments in mandibular bone graft procedures and are used in conjunction with rigid internal fixation

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-**LactoSorb® RC Buttress (K991009)** is intended for use to protect the suture during its use in transosseous bone tunneling in the repair of rotator cuff tears of the shoulder.

Basis of Substantial Equivalence:

In terms of overall design and intended use, the LactoSorb® plates, meshes, and panels/sheets are equivalent to their preceding 510(k)s. The only modification made was to the package insert which now includes the use of a hot sterile saline/water bath to heat and contour LactoSorb®. Previously, only the use of LactoSorb® Heat Packs was advised. Mechanical testing has been included to show substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2001

Ms. Dalene T. Binkley
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46582

Re: K011237
Trade Name: LactoSorb® Plates, Meshes and Panels/Sheets
Regulation Number: 888.3030
Regulatory Class: II
Product Code: HRS
Dated: April 17, 2001
Received: April 23, 2001

Dear Ms. Binkley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K011237

DEVICE NAME: LactoSorb® Plates, Meshes, and Panels/Sheets

INDICATIONS FOR USE:

-LactoSorb® Trauma Plating System (K955729 and K960988):

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.
3) Trauma of the midface or craniofacial skeleton.
4) Reconstructive procedures of the midface or craniofacial skeleton.

-LactoSorb® Trauma Plating System (K992355 and K971870):

A. General Indication: trauma procedure of the midface or craniofacial skeleton.

Specific Indications:

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.
3) Pediatric midface or craniofacial trauma
4) LeFort (I, II, III) fractures
5) Orbital floor fractures
6) Fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
7) Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2) LeFort (I, II, III) fractures
3) Tumor reconstruction in midface or craniofacial procedures
4) Bone graft procedures in the midface or craniofacial skeleton
5) Pediatric reconstructive procedures
6) Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
7) Craniotomy flap fixation

for Mark N Milhe

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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510(k) Number K011237

-LactoSorb® Panels (K974309):

A. General Indication: trauma procedure of the midface or craniofacial skeleton.

Specific Indications:

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.
3) Pediatric midface or craniofacial trauma
4) Orbital floor fractures
5)Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2) Tumor reconstruction in midface or craniofacial procedures
3) Bone graft procedures in the midface or craniofacial skeleton
4) Pediatric reconstructive procedures
5) Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
6) Craniotomy flap fixation

-LactoSorb® Panels and Fasteners (K980927) are used to maintain the position of bone fragments in mandibular bone graft procedures and are used in conjunction with rigid internal fixation.

-LactoSorb® Panels and Fasteners (K984390) are used in maintaining the position of bony fragments in pelvic reconstructive procedures. This product is not intended for use in the spine or joint space.

-LactoSorb® Hand System (K991763) is indicated for surgical fixation of closed non-comminuted diaphyseal metacarpal fractures in the presence of appropriate immobilization.

-LactoSorb® Sheets (K992158):

A. General Indication: trauma procedure of the midface or craniofacial skeleton.

Specific Indications:

1) Comminuted fractures of the naso-ethmoidal and infraorbital areas.
2) Comminuted fractures of the frontal sinus wall.

for Mark N Milham
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Division of General, Restorative
and Neurological Devices

510(k) Number K011237

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3) Pediatric midface or craniofacial trauma
4) Orbital floor fractures
5) Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

Specific Indications:

1) Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2) Tumor reconstruction in midface or craniofacial procedures
3) Bone graft procedures in the midface or craniofacial skeleton
4) Pediatric reconstructive procedures
5) Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
6) Craniotomy flap fixation

C. Mandible Indication: Used to maintain the position of bony fragments in mandibular bone graft procedures and are used in conjunction with rigid internal fixation

-**LactoSorb® RC Buttress (K991009)** is intended for use to protect the suture during its use in transosseous bone tunneling in the repair of rotator cuff tears of the shoulder.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____ (Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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510(k) Number K011237